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Atty. Dkt. No. 091856-0111

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: GEMMA ET AL.  
Title: CRYSTALLINE PAROXETINE METHANE SULFONATE  
Patent No.: 7,598,271  
Issue Date: 10/06/2009  
Examiner: Celia Chang  
Art Unit: 1625  
Confirmation Number: 9739

**RENEWED REQUEST FOR RECONSIDERATION OF PTA  
UNDER 37 C.F.R. §1.705 & RESPONSE TO DECISION ON PETITION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the communication mailed August 26, 2009 (copy attached), that dismissed Applicants' Request for Reconsideration of Patent Term Adjustment for the captioned patent filed May 21, 2009, Applicants hereby *renew* that portion of their Request that was dismissed as premature and *request reconsideration* of that portion of their Request that was dismissed on the merits.

**PTA Due To PTO Failure to Issue Patent Within Three Years (§ 1.702(b) Delay)**

The communication notes that Applicants' Request for Reconsideration of PTA relates in part to the PTO's failure to issue the patent within 3 years of the filing date, and states that the Office's computers will not undertake the 37 CFR § 1.702(b) calculation until the actual date of

issuance has been determined, even when an RCE has been filed that stops the accrual of additional PTA under § 1.702(b). Thus, the communication finds Applicants' request for reconsideration on this ground "premature," and states that such requests should be filed after the patent grants, within two months of the grant date, under § 1.705(d).

The patent at issue granted October 6, 2009; thus, this renewed Request for Reconsideration is timely filed within two months of the grant date.

As set forth in Applicants' original Request for Reconsideration of PTA, Applicants believe that the PTA determination for the patent was made in accordance with the "Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A)" published at 69 Fed. Reg. 34238 (Jun. 21, 2004). Under that interpretation of the PTA statute, any PTO delay under 35 U.S.C. § 154(b)(1)(A) is deemed to overlap with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B), and so, as a practical effect, PTA may be awarded under § 154(b)(1)(A) or § 154(b)(1)(B), but not both.

On September 30, 2008, the United States District Court for the District of Columbia issued a decision finding that the U.S. Patent and Trademark Office's interpretation of the PTA statute is incorrect. *Wyeth v. Dudas*, Civ. Action No. 07-1492 (JR) (Sep. 30, 2008). The court determined that, under the correct interpretation of the PTA statute, periods of "overlap" are limited to "periods of time . . . [that] occur on the same day." *Wyeth*, slip op. at 8. Thus, a PTO delay under § 154(b)(1)(A) overlaps with a delay under § 154(b)(1)(B) only if the delays "occur on the same day." *Id.* Because the Office's determination of PTA did not comport with the district court's statutory construction, Applicants respectfully urge that the PTA for the patent be recalculated in accordance with the *Wyeth* holding, as outlined below. Although the Office appealed the *Wyeth* decision and that appeal is pending at the Federal Circuit, unless and until the Federal Circuit reverses or vacates the district court decision, that decision is binding on the Office.

**PTA Due To PTO Delay During Prosecution (§ 1.702(a) Delay)**

Applicants' Request for Reconsideration of PTA also relates to the PTO's failure to award PTA based on PTO delay during prosecution, namely, the PTO's failure to issue an Office Action under 35 U.S.C. § 132 or a Notice of Allowance under 35 U.S.C. 151 within four months of the Reply filed by Applicants on May 31, 2001 (a Response to Restriction Requirement), which delay is awarded under 37 CFR § 1.702(a). That delay starts September 30, 2001 (four months after the Reply) and extends through September 19, 2008, when the PTO issued a Notice of Allowance, which was the first notice issued by the PTO that "stops the clock" under § 1.702(a) after Applicants' May 31, 2001 Reply.

The Office alleges that the Notice of Suspension mailed August 2, 2001<sup>1</sup> is a "notification under 35 U.S.C. § 132" that "stops the clock for determining examination delay" under § 1.703(a)(2), which allegedly did not start running again until the favorable decision by the Board of Patent Appeals and Interferences issued on May 25, 2004.

The Office cites no authority for its position that the Notice of Suspension is an action "under 35 U.S.C. § 132." Indeed, the Office's position that the Notice of Suspension constitutes a notification under 35 U.C.S. § 132 that "stops the clock" under § 1.703(a)(2) is contrary to the plain language of 37 C.F.R. § 1.703(a)(2) and 35 U.S.C. § 132.

According to 37 C.F.R. § 1.703(a)(2):

"The period of adjustment under § 1.702(a) is the sum of the following periods . . . (2) The number of days, if any in the period

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<sup>1</sup> The Notice of Suspension is incorrectly classified as a "Letter Suspending Prosecution At Applicant's Request." As set forth in the "Request for Clarification of Suspension Letter" filed August 28, 2001, Applicants did not request suspension of prosecution. Applicants had previously raised the possibility of an interference in a paper filed January 31, 2001, and the PTO suspended prosecution "[d]ue to a potential interference" on February 21, 2001. However, the Office Action mailed April 21, 2001 reopened prosecution. Applicants replied to that Action on the merits, and did not thereafter request suspension of prosecution or declaration of an interference. Thus, the suspension was PTO-initiated, not applicant-initiated.

beginning on the day after the date that is four months after the date a reply under § 1.111 was filed and ending on the date of mailing of either *an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151*, whichever occurs first....

An action under § 132 must include a rejection, objection or requirement to which an applicant must reply in order to continue prosecution:

Whenever, on examination, any claim for a patent is **rejected, or any objection or requirement made**, the Director shall notify the applicant thereof, stating the reasons for such **rejection, or objection or requirement**, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, **the application shall be reexamined....**

35 U.S.C. § 132(a) (emphasis added).

The Notice of Suspension did not include any “rejection or objection or requirement.” To the contrary, it stated that the pending claims “are allowable,” but that “due to a potential interference, *ex parte* prosecution is suspended.” Moreover, the Notice of Suspension did not require any reply from Applicants, or set any time period for reply. Thus, it does not have any of the hallmarks of a notice under 35 U.S.C. § 132.

That the Notice of Suspension should not “stop the clock” of PTO delay under § 1.703(a)(2) is further underscored by the fact that Applicants could have done nothing to advance prosecution at that point. Indeed, prosecution had been suspended. A suspension of prosecution cannot constitute an action under § 132 merely because the PTO initiated the suspension. To the contrary, a suspension of action is a delay caused by the PTO, and the Notice of Suspension serves only as an express admission of the PTO’s delay. No provision of the Patent Term Adjustment rules allows the PTO to overlook such delay.

Treating the Notice of Suspension as an action that “stops the clock” under § 1.703(a)(2) also is inconsistent with MPEP § 709(II), which states that “[s]uspension of action at the initiative of the Office should be avoided, if possible, because such suspension will cause delays

in examination . . . and may lead to . . . patent term extension, or adjustment, due to the suspension.” Thus, the MPEP expressly contemplates that PTO-initiated suspensions, such as that at issue here, constitute PTO delay that should be counted towards PTA.

### **III. Summary and Calculation of PTA**

In view of the foregoing, Applicants have recalculated PTA for the captioned patent under the *Wyeth* court’s interpretation of 37 CFR §§1.703(b) and without treating the Notice of Suspension as an action under 35 U.S.C. § 132, and have determined that the patent is entitled to a total of 2514 days PTA, as shown on the attached sheet, which shows the relevant delays under 37 CFR §§1.702(a), (b) and (c), 37 CFR §§1.703(a), (b) and (c), and 37 CFR § 1.704(c). Applicants therefore respectfully request that the application be accorded **2514 days PTA**.

Specifically, 2,546 days of PTA should be accorded under 37 CFR § 1.702(a) and 37 CFR §1.703(a)(2) due to the Office delay beginning on September 30, 2001, which was four months after the Applicants filed a response to the Restriction Requirement, and ending on the day the Notice of Allowance was issued on September 19, 2008. Additionally, 33 days of PTA should be accorded under 37 CFR § 1.702(a) and 37 CFR §1.703(a)(6) due to the PTO’s failure to issue the patent within four months of the issue fee payment made October 1, 2008, until Applicants filed a Request for Deferral of Issuance on March 6, 2009. Further, 15 days of PTA should be accorded under 37 CFR § 1.702(a) and 37 CFR §1.703(a)(6) due to the PTO’s failure to issue the patent within four months of the issue fee payment made May 21, 2009, until the patent issued in October 6, 2009.

Additionally, 135 days of PTA should be accorded under 37 CFR § 1.702(b) and 37 CFR §1.703(b)(2) due to the PTO’s failure to issue the patent within three years, not including the time consumed by the interference, taking into account periods of overlapping delay under

37 CFR §1.702(a) (as interpreted by the *Wyeth* district court), and not including time consumed by the Request for Continued Examination filed March 6, 2009.<sup>2</sup>

The delay due to the interference (603 days) overlaps entirely with the 2,546 day period of delay requested under 37 CFR § 1.702(a) and 37 CFR §1.703(a)(2), and so is accounted for above. Should the Office determine that Applicants are not entitled to PTA for the full 2,546 day period, the Office must ensure that Applicants are credited for the full period of delay due to the interference, as required by 37 CFR § 1.702(c) and 37 CFR § 1.703(c)(1).

Finally, Applicants note that, under 37 CFR §1.704(c)(2), 215 days of Applicant delay may need to be deducted from the total PTA due to Applicants' request for Deferral of Issuance filed March 6, 2009, although it is not clear that that provision applies when accrual of PTO delay under 37 CFR §1.703(b)(2) has been tolled by the filing of an RCE on the same date.

Thus, Applicants request that the application be accorded **2514 days PTA**.

The patent is not subject to a terminal disclaimer. A terminal disclaimer was filed in the application; however, a petition to withdraw the Terminal Disclaimer was granted on April 16, 2008.

Applicants request further that a decision on the portion of the delay requested under 37 CFR §1.703(b) (135 days) be **deferred or delayed** until a final decision has been rendered in *Wyeth v. Dudas*, which is now on appeal at the U.S. Court of Appeals for the Federal Circuit, under Federal Circuit Docket No. 2009-1120.

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<sup>2</sup> Applicants' original Request for Reconsideration stated that 168 days delay was due under 37 CFR §1.703(b)(2); however, having reviewed the PTA rules, Applicants believe that 33 days of PTA previously requested under 37 CFR §1.703(b)(2) should be accorded under 37 CFR §1.703(a)(6) due to the PTO's failure to issue the patent within four months of the issue fee payment made October 1, 2008, before the Request for Deferral of Issuance filed March 6, 2009.

Applicants believe no additional fee is due for this renewed petition and request for reconsideration. However, the Commissioner is authorized to charge any fees which may be due, or credit any overpayment, to Deposit Account No. 19-0741.

Respectfully submitted,

Date October 22, 2009

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 295-4094  
Facsimile: (202) 672-5399

By Courtenay C. Brinckerhoff

Courtenay C. Brinckerhoff  
Attorney for Applicant  
Registration No. 37,288

## Patent Term Adjustment Calculation System

Add a new event to this case

Docket Number: 091856-0111  
Application Number: 09/200743  
Patent Number: N/A

	Event Description	Event Date	Days from Filing	PTO Days	Applicant Days
Edit Delete	Application Filing Date	11/27/2000	0		
Edit Delete	Restriction Requirement	04/26/2001	150		
Edit Delete	Restriction Requirement Response Received at PTO	05/31/2001	185		
	Restriction Requirement Response Filed + 4 months	09/30/2001	307		
Edit Delete	IDS NOT falling under 1.704(c)(6), (8) or (10) filed at PTO	03/20/2002	478		
Edit Delete	Interference Declared	10/01/2002	673		
	3 Year Period Starts	11/27/2003	1,095		
Edit Delete	Interference Decided	05/25/2004	1,275	(603)	
Edit Delete	Notice of Allowance	09/19/2008	2,853	(2546)	
Edit Delete	Issue Fee Paid	10/01/2008	2,865		
	Issue Fee Paid + 4 months	02/01/2009	2,988		
Edit Delete	Request for Deferral of Issuance received at PTO	03/06/2009	3,021	(33),(33)	
Edit Delete	Request For Continued Examination (including amendment)	03/06/2009	3,021	(1926) 2714	
	3 Year Period Stopped	03/06/2009	3,021		
Edit Delete	Notice of Allowance	04/17/2009	3,063		
Edit Delete	Issue Fee Paid	05/21/2009	3,097		
	Issue Fee Paid + 4 months	09/21/2009	3,220		
Edit Delete	Patent Grant Date	10/06/2009	3,235	(15),(15) 15	215
			Totals:	2,729	215
			PTA:	2,514	





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AUG 26 2009

**OFFICE OF PETITIONS**

FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON DC 20007

In re Application of :  
Benneker et al. :  
Application No. 09/200,743 : ON APPLICATION FOR  
Filed: November 30, 1998 : PATENT TERM ADJUSTMENT  
Atty Docket No. 091856-0111 :  
Title: CRYSTALLINE PAROXETINE :  
METHANE SULFONATE :

This is in response to the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705," filed May 21, 2009. Applicant submits that the correct patent term adjustment to be indicated on the patent is two thousand, seven hundred and fourteen (2714) days, not two thousand and fifty-seven (2057) days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicant requests this correction partly on the basis that the Office will take in excess of three years to issue this patent.

In addition, applicants assert that the recalculation of the patent term adjustment as set forth in a letter regarding patent term adjustment (mailed on February 10, 2009) was made in error.

To the extent that the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is DISMISSED as PREMATURE.

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not

undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, applicant is advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. However, as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicant must timely file an application for patent term adjustment prior to the payment of the issue fee<sup>1</sup>.

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<sup>1</sup> For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the §1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e) for consideration of the application for patent term adjustment under 37 CFR 1.705(b).

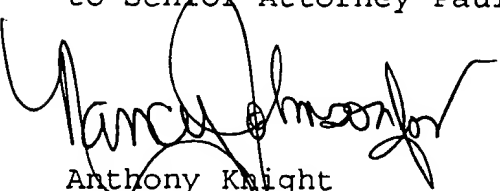
Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d) and must include payment of the required fee under 37 CFR 1.18(e).

To the extent that Applicants otherwise request review of the the recalculation of the patent term adjustment as set forth in the February 10, 2009 letter regarding patent term adjustment, the request is **DISMISSED**.

Applicant's assertion has been considered, but is not well taken. The reply to the restriction requirement was filed on May 31, 2001. The Letter regarding the Request for Suspension was mailed on August 2, 2001 in response to, and within four months of, the filing of the reply. Further, a review of the Letter regarding the Request for Suspension confirms that it is an Office action prepared by the Examiner as a result of the examination conducted pursuant to 35 U.S.C. 131. The Letter regarding the Request for Suspension is a notification under 35 U.S.C. 132 and properly stops the clock for determining examination delay pursuant to 37 CFR 1.703(a)(2).

The Office of Data Management has been advised of this decision. This application is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries regarding this decision should be directed to Senior Attorney Paul Shanowski at (571) 272-3225.



Anthony Knight  
Supervisor  
Office of Petitions